

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

**Antimicrobials Division (AD)**

April 8, 2013

DP BARCODE(s): 407482

MRID(s) : 48992201, 48992204, 49042401, 49042402

Supplemental MRIDs 49090001 and 49090003

**SUBJECT:**

(Name of Product) Pathex Antimicrobial Filter Media

FILE SYMBOL: 88965-R

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ]

OR

End-use Product [ X ]

**INGREDIENTS:**

<u>PC Code</u>	<u>CAS #</u>	<u>Ingredient Name</u>
107403	199111-50-7	1-Octadecanaminium,N,N-dimethyl-N-[3-(trihydroxysilyl)propyl],chloride

TEST LAB: American Analytical Laboratories  
Product Safety Laboratory

SUBMITTER: A S Filtration, Inc..

GUIDELINE: Product Chemistry Groups A and B

ORGANIZATION: AD\PSB\CTT

REVIEWER: Earl Goad

APPROVED BY: Karen P. Hicks

DATE APPROVED: April 8, 2013

COMMENT:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
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April 8, 2013

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA File Symbol. 88965-R  
Product Name: Pathex Antimicrobial Filter Media  
DP Barcode(s): 407482

CODE: (A540) New Product

DATE DUE: May 6, 2013

FROM: Earl Goad, Biologist  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

Two handwritten signatures are present. The top signature is in black ink and appears to be "Earl Goad". The bottom signature is in blue ink and is more stylized, possibly reading "Karen Hicks".

THRU: Karen Hicks, Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

TO: Velma Noble PM#31/Cletis Mixon  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Applicant: A S Filtration, Inc.

PRODUCT FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
3-(Trihydroxysilyl) propyldimethyloctadecyl ammonium chloride	0.05
<u>Other Ingredient(s):</u>	<u>99.95</u>
Total:	100.00

\*Inert ingredient information may be entitled to confidential treatment\*

BACKGROUND:

On behalf of A S Filtration, LLC, toXcel, LLC has submitted an application to register their new product "Pathex Antimicrobial Filter Media" EPA File Symbol 88965-R. The product is produced by coupling the active ingredient from a registered source to silica sand. The proposed label describes the use of the product is for "reduction and control of waterborne bacteria in storm water, industrial, agricultural systems, and water destined for routine water purification. The product is produced from an EPA registered source.

The data package includes.

1. Cover and study transmittal letter from toXcel LLC dated November 13, 2012.
2. EPA Forms: 8570-1(Application), 8570-34 (certification for Data Citation), 8570-27(Formulators Exemption), and 8570-35 (Data Matrix) dated November 9, 2012.
3. Original Confidential Statements of Formula for Basic [REDACTED] Alternate [REDACTED] and Alternate [REDACTED] dated November 9, 2012. Proposed Product Label dated November 8, 2012.
4. Communication from Mike Kelly (toXcel LLC) to Velma Noble (EPA) dated January 23, 2013 including three attachments: (1) Method Development – PSL study number 34896,(2) Revised CSFs, (3) Analytical Industrial Research Laboratories Pathex QC Reports.
5. Communication from Mike Kelly (toXcel LLC) to Earl Goad dated January 25, 2013.
6. Replacement Confidential Statements of Formula for Basic [REDACTED] Alternate [REDACTED] and Alternate [REDACTED] dated January 23, 2013.
7. Final Revised CSFs for Basic [REDACTED] Alternate [REDACTED] and Alternate [REDACTED] Dated March 26, 2013.
8. Three Product Chemistry Studies.

MRID	Citation	
48992201	Burnside, C. (2012) Pathex Antimicrobial Filter Media: Product Chemistry. Unpublished study prepared by ToXcel, LLC. 128p.	13-Nov-2012
48992204	Kelley, J. (2012) Pathex - Overview of Product Performance. Unpublished study prepared by ToXcel, LLC. 28p.	13-Nov-2012
49042401	Burnside, C. (2013) Product Chemistry Data - Product Identity, Composition, Analysis, and Physical/Chemical Characteristics: Final Report. Unpublished study prepared by ToXcel, LLC. 7p. (Addendum to MRID# 48992201)	23-Jan-2013
49090001	Patterson, R. (2013) Pathex Antimicrobial Filter Media: Preliminary Analysis and Enforcement Analytical Method: Supplemental Data to Support MRID 48992201. Unpublished study prepared by Analytical Industrial Research Laboratories. 64p.	27-Mar-2013
49090003	Burnside, C.; Kelley, M. (2013) Pathex Antimicrobial Filter Media: Addendum to MRID 48992201: Correspondence Regarding EPA Review of Product Chemistry Data. Unpublished study prepared by ToXcel, LLC. 13p.	27-Mar-2013



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\*Manufacturing process information may be entitled to confidential treatment\*

#### FINDINGS:

1. Confidential Statement of Formula. The nominal concentration of the bound active ingredient on the CSF and label is based on the analytic determination rather than based on proportional formulation from a known EPA registered source of active. The final revised CSFs for the basic [REDACTED] alternate [REDACTED] and alternate [REDACTED] are dated March 26, 2013. Wider certified limits were requested based on the heterogeneity of the ingredients and the imprecision of the analytical method. These revised CSFs and the wider certified limits are acceptable.
2. Proposed Product Label: The chemistry portions of the product label appear to be accurate and complete.
3. Product Chemistry Groups A and B.
  - a. Enforcement analytical method (Guideline 830.1800) and a (Guideline 830.1700) preliminary analysis were provided with the submission.
    - i. Because only a portion of the silyl quat active ingredient from the registered source product is bound to the sand, analysis of the sand was required to determine the % wgt of active in the final product.
    - ii. The analysis performed, was to estimate the amount of active based on determination of the presence of a [REDACTED] constituent of that active ingredient.
    - iii. The same method was used and validated as the analytical enforcement method for use with this product.
    - iv. It was found that these methods overestimated the concentration of active in the product due to the presence of a [REDACTED] containing impurity in the source product which also bound to the sand. Subsequent to this finding, the preliminary analysis data was recalculated to take this into account.
    - v. The preliminary analysis as well as the enforcement method was found to be acceptable though not as precise as traditional titration methods for quaternary compounds.
  - b. A standard one year storage stability and corrosion characteristic studies were not provided with the submission. Considering the nature of this product and its use pattern, this may be replaced by an accelerated storage stability study. This study is suitable for this product due to its solid state properties and low volatility of the active ingredient. The study is described in the website link:

<http://www.epa.gov/pesticides/regulating/final-signed-acc-ss-cc-memo.pdf>

#### CONCLUSION:

The revised basic [REDACTED] Alternate [REDACTED] and Alternate [REDACTED] CSFs dated March 26, 2013 and the proposed product label are found to be acceptable. Except for the product storage stability and corrosion characteristics, that is in process, the product chemistry groups A and B data requirements have been satisfied.

## PRODUCT CHEMISTRY REVIEW

### I. CONFIDENTIAL STATEMENT OF FORMULA

#### a. Type of formulation and source registration:

- |                                     |   |  |
|-------------------------------------|---|--|
| • Non-integrated formulation system | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/>            |
| • Are all TGAs used registered?     | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/>            |
| • Integrated formulation system     | Yes <input type="checkbox"/>            | No <input checked="" type="checkbox"/> |

#### b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§180.940 and 180.950.

Yes ☐ No ☒

*Note: This product is not intended for food use. All inert ingredients have PC codes. All formulation components are listed on the EPA document "Inert Ingredients Permitted for Use in Nonfood Use Pesticide Products," available at [http://www.epa.gov/opprd001/inerts/inert\\_nonfooduse.pdf](http://www.epa.gov/opprd001/inerts/inert_nonfooduse.pdf).*

#### c. Physical state of product:

*Solid (Sand)*

#### d. The chemical IDs and analytical information (including that for the TGAs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes ☒ No ☐

#### e. The NCs and CLs are acceptable.

Yes ☒ No ☐

**Note:** Request for wider certified limits were based on the based on the heterogeneity of the product and the imprecision of the analytical method used to evaluate the concentration of the product.

#### f. Active ingredients

<u>Active Ingredient</u>	<u>Nominal%</u>	<u>Lower CL%</u>	<u>Upper CL %</u>
1-Octadecanaminium,N,N-dimethyl-N-[3-(trihydroxysilyl) propyl],chloride	0.05	0.02	0.08

#### g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?  
Yes ☐ No ☐ Not applicable ☒
- Have all impurities of  $\geq 0.1\%$  in the product been identified?  
Yes ☐ No ☐ Not applicable ☒

II PRODUCT LABEL

a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- |  |         |        |
|--|---------|--------|
| • 10% or more of a petroleum distillate: | Yes [ ] | No [X] |
| • 1.0% or more of methyl alcohol:        | Yes [ ] | No [X] |
| • sodium nitrite at any level:           | Yes [ ] | No [X] |
| • a toxic List 1 inert at any level:     | Yes [ ] | No [X] |
| • arsenic in any form:                   | Yes [ ] | No [X] |

a. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?

Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [x] No [ ]

*Note: A 1 year GLP-compliant storage and corrosion characteristic or equivalent accelerated storage stability studies are required.*



**Table A:**  
**Product Chemistry (Series 830, Group A)**

<b>Data Requirements</b>	<b>Acceptance of Information</b>	<b>MRID No.</b>
830.1550 Product Identity <sup>1</sup>	A	48992201 and CSF
830.1600 Description of Materials	A	48992201 and CSF
830.1620 Production Process <sup>2</sup>	NA	
830.1650 Formulation Process <sup>3</sup>	A	48992201
830.1670 Formation of Impurities <sup>4</sup>	A	48992201 and 49042401
830.1700 Preliminary Analysis <sup>5</sup>	<i>Provided because only a proportion of the active ingredient bound silica substrate</i>	48992201 and Supplemental 49090001 49090002
830.1750 Certified Limits <sup>6</sup>	A – Wider certified limits were proposed, base on imprecision of analytic method EPA standard certified limits. A signed certification statement was provided, as requested under OPPTS 830.1750(g).	48992201
830.1800 Enforcement Analytical Method <sup>7</sup>	A – Analysis of Chloride content by titration/ion spectrophotometric method analysis after oxygen bomb combustion.	48992201 And Supplemental 49090001 49090002
830.1900 Submittal of Samples	<i>[Samples are to be provided on a case-by-case basis for end-use products.]</i>	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

<sup>1</sup>See Confidential Appendix A for additional information.

<sup>2</sup>For MP/EP products produced by an integrated formulation system.

<sup>3</sup>For products from a TGAI or MP.

<sup>4</sup>May be waived unless actual/possible impurities are of toxicological concern.

<sup>5</sup>Five batch analysis required for products produced by an integrated formulation system.

<sup>6</sup>If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

<sup>7</sup>Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

**Table B:**  
**Physical and Chemical Characteristics (Series 830, Group B)**

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	Tan-white	48992201
830.6303 Physical State	A	Solid (sand)	48992201
830.6304 Odor	A	Practically odorless	48992201
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	<i>[Not required for end-use products.]</i>	
830.6314 Oxidation/Reduction; Chemical Incompatibility	NA	Does not contain an oxidizing or reducing agent	48992201
830.6315 Flammability/Flame Extension	NA	Does not contain combustible materials	48992201
830.6316 Explodability	NA	The product does not contain an explosive material.	48992201
830.6317 Storage Stability	G	AIRL Study # 243172 cited as showing stability of several lots over a year but does not follow as a guideline study. Recommend an accelerated storage stability.	48992201
830.6319 Miscibility <sup>1</sup>	A	Not an emulsifiable liquid will not be diluted with petroleum solvents	48992201
830.6320 Corrosion Characteristics	A	Product is predominantly Silicon dioxide non reactive to plastic packaging	48992201
830.6321 Dielectric Breakdown Voltage	A	NA -The end use product is not intended for use in or around electrical equipment.	48992201
830.7000 pH <sup>2</sup>	A	The pH 6.43	48992201
830.7050 UV/Visible Absorption	NA	<i>[Not required for end-use products.]</i>	
830.7100 Viscosity	NA	NA- product is solid granular	
830.7200 Melting Point/Melting Range	NA	<i>[Not required for end-use products.]</i>	



Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7220 Boiling Point/Boiling Range	NA	[Not required for end-use products.]	
830.7300 Density/Relative Density/Bulk Density	A	Pour Density 1.404 g/mL, Tap density 1.468 g/mL	48992201
830.7370 Dissociation Constants in Water	NA	[Not required for end-use products.]	
830.7550/830.7560/830.7570 Partition Coefficient	NA	[Not required for end-use products.]	
830.7840/830.7860 Water Solubility	NA	[Not required for end-use products.]	
830.7950 Vapor Pressure	NA	[Not required for end-use products.]	

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\* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

<sup>1</sup>If product is an emulsifiable liquid

<sup>2</sup>If product is dispersible with water